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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,070	12/13/2006	Roger C. Adami	PC25670A	5146

28523 7590 06/23/2010

PFIZER INC.
PATENT DEPARTMENT
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GROTON, CT 06340

EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
06/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,070	ADAMI ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-16,19,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13-16,19,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 11, 13-16, 19, 28 and 29 are pending in this application.

Applicants' arguments filed March 25, 2010 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 13-16, 19 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giles-Komar et al. U.S. Patent No. 7,163,681 B2 and Pfizer Products Inc. WO 03/009848 A1 (IDS dated 3/13/07) and further in view of Ono et al. Eur. J. Pharm. Sci. 1999 (U).

One applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Giles-Komar et al. teach a pharmaceutical composition comprising a β cyclodextrin such as 2-hydroxypropyl β cyclodextrin (column 43, lines 11-12) and other pharmaceutical excipients or additives that are suitable for use (column 43, lines 18-28) and further comprising a preservative such as m-cresol. (column 44, lines 24-35). Pfizer Products Inc. teach tachykinin antagonists (NK-1 receptor antagonists) encompassing formula (1a) (page 12 lines 29-31), and sulfobutyl ether β cyclodextrin (see example 1, page 16). Further, Pfizer Products, Inc. teaches that these NK-1 receptor antagonists can be administered parenterally (page 12, lines 10-11 and example 1 page 16).

Pfizer Products Inc. does not teach the compound of formula (1a) that is preserved with meta-cresol specifically. Giles-Komar et al. teach a β-cyclodextrin composition with an active agent that is preserved with m-cresol (meta-cresol) and Pfizer Products Inc. teaches the specific compound in a cyclodextrin composition with a different preservative. Claim 19 is drawn to a specific amount of meta-cresol preservative in the β cyclodextrin composition and the specific binding value indicating the amount of preservative that is unsequestered. Ono et al. teach the formula by which one having ordinary skill in the art could readily calculate such binding values (see pages 135-136).

I would have been obvious to employ the composition of formula (1a) with a preservative such as m-cresol and a β cyclodextrin motivated by the teaching of Giles-Komar et al. who teaches a successful combination of β-cyclodextrin and m-cresol and Pfizer Products Inc. who discloses a formulation with the compound of formula (1a) combined with sulfobutyl ether β cyclodextrin and a preservative, armed with the formula of Ono to assure that the correct amount of β cyclodextrin is employed so as to prevent inclusion complexes and ensure solubility, stability and bioavailability (page 133, column 1). Addressing instant claim 29, methods of using the NK-1 receptor antagonists of formula 1a are disclosed in Pfizer Products Inc. for the treatment of vomiting (emesis) in companion animals such as dogs (page 3, line 6), in view of the obviousness rejection supra.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Arguments

Applicant's arguments filed March 25, 2010 have been fully considered but they are not persuasive. Applicant argues that Giles-Komar recites isolated human anti-integrin α-V subunit antibodies, immunoglobulin and cleavage products, compositions thereof for the treatment of cell adhesion diseases involving α-V integrin mediated angiogenesis arguing that the citation provides a discussion of thousands of potential

formulation permutations using antimicrobial agents and cyclodextrin. With regard to Applicants' argument that the examiner has merely looked over the list of hundreds of excipients and highlighted two of which are common with the instant invention, "[I]n a section 103 inquiry, 'the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.'" *Merck & Co. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976)); *see also In re Mills*, 470 F.2d 649, 651 (CCPA 1972) ("All the disclosures in a reference must be evaluated, including nonpreferred embodiments, and a reference is not limited to the disclosure of specific working examples." (citations omitted)). Neither the Patent Act nor the case law requires a description of the exact chemical component of each combination that falls within the claimed ranges. *Union Oil Co. of Calif. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 USPQ2d 1227 (Fed. Cir. 2000). Further, Applicant cites Pfizer Inc., v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007) wherein the court found that an "obvious to try" approach was obvious when a finite number (n=53) of predictable solutions was disclosed. In this case, Giles-Komar et al. teach the cyclodextrin excipients/additive (column 43, lines 20-21) along with about three other excipients i.e. polyvinylpyrrolidones and polyethylene glycols. and teach preservatives for the formulation selected from cresols (ortho, meta, para and chloro) and other well known preservatives such as benzyl alcohol, phenylmercuric nitrite, phenoxyethanol, formaldehyde, chlorobutanol, magnesium chloride, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate and thiomersol (column 43,

lines 40-45). This reference clearly teaches that cyclodextrins such as sulfobutyl ether β cyclodextrin are compatible with a meta-cresol preservative. This appears to be a finite number of solutions and it is less than the 53 possible solutions of Pfizer Inc., v. Apotex, Inc., cited. Bronk teaches the compound of formula (Ia) and teaches the formulation in cyclodextrin and a preservative. It would have been obvious to employ the composition of formula (1a) with a preservative such as m-cresol and a β cyclodextrin motivated by the teaching of Giles-Komar et al. who teaches a successful combination of β-cyclodextrin and m-cresol and Pfizer Products Inc. who discloses a formulation with the compound of formula (1a) combined with sulfobutyl ether β cyclodextrin and a preservative, equipped with the formula of Ono et al. to assure that the correct amount of β cyclodextrin is employed so as to prevent inclusion complexes and ensure solubility, stability and bioavailability (page 133, column 1). Applicant asserts that the examiner succumbed to hindsight by merely picking two of the excipients from the enormous pool of options. In response, Bronk specifically teach the compound formulated with cyclodextrin and a preservative although the preservative is not meta cresol. Giles-Komar et al. teaches that the agents cited can be formulated with cyclodextrin and preservatives such as meta cresol. Regarding the issue of complexation, one having ordinary skill in the art could readily determine the amount of cyclodextrin and preservative when bolstered with the formula such as that in Ono et al. who teach the formula by which one having ordinary skill in the art could readily calculate such binding values. Applicant states that Bronk discloses the use of a compound of formula Ia only in a parenteral formulation comprising either sesame or

peanut oil in aqueous propylene glycol. In response, Bronk teaches a formulation comprising 20% SBE cyclodextrin (see example 1, page 16). Applicant argues that Ono et al. recites complexation issues relative to the use of cyclodextrins particularly as they relate to the solubility and permeation of phenacetin and various benzoic acids. In response, Ono et al. uses phenacetin and benzoic acids as a model for "guest molecules" (see abstract). Phenacetin and benzoic acid derivatives were employed as the **model** drug and competing agents because they are known to form 1:1 inclusion complexes with β-CyD (page 134, column 1, paragraph 1). These agents were employed to justify the validity of the method and to gain **an insight into the permeation mechanism of drugs**. Not just phenacetin and benzoic acid derivatives.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

Donna Jagoe /D. J./
Examiner
Art Unit 1619

June 11, 2010